



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/682,067 | 10/09/2003 | Mark B. Knudson | 11587.1USCA | 9479 |
| 22852 | 7590 | 12/21/2006 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | ISABELLA, DAVID J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 12/21/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/682,067 | KNUDSON ET AL. |
| | Examiner | Art Unit |
| | DAVID J. ISABELLA | 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 October 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-25,31,33-41,43-51 and 53-64 is/are pending in the application.
 4a) Of the above claim(s) 17,23 and 25 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 16,18-22,24,31,33-41,43-51 and 53-64 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Applicant's amendment filed on 10/10/2006 has been entered.

Claims 1-15,26-30,32,42, and 52 have been cancelled. Currently, claims 16-25, 31,33-41,43-51,53-64 with claims 17,23 and 25 remain withdrawn; and claims 16,18-22,24 and 31,33-41,43-51,53-64 are pending for action.

Response to Arguments

Applicant's arguments filed 10/13/2006 have been fully considered but they are not persuasive.

The language "for use in a wall of a heart" and "adapted to positioned in the heart wall between a coronary vessel and a chamber in the heart" is directed to a method for using the "bypass conduit" and does not, in itself serve to further limit the structure of the conduit. Lazarus discloses a conduit that is for use in a lumen (eg. blood vessel or artery). The properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart. Applicant argues that Lazarus is silent as to the sufficiently rigid to remain open during both systole and diastole. If the vessel of Lazarus did not possess sufficient rigidity, the vessel would collapse and not perform the function of a conduit for blood flow. Though Lazarus is silent as to the rigidity, it appears that when used in the vascular system the vessel remains open during both cycles of the heart. There is no disclosure in Lazarus which would preclude the use of the vessel in the wall of the heart, and therefor, the vessel of Lazarus is capable of performing the recited function.

Applicant argues that the material of Lazarus is not necessarily material that could remain open in a heart wall during both systole and diastole, however applicant's device utilizes the same materials for the claimed conduit. And even if applicant can properly establish that vessel of Lazarus would not remain open during both heart cycle, applicant has failed to adequately argue the combination of Lazarus in view of Robinson, Lee and Bowen. Each of the secondary references teaches the use of reinforcing members, similar to that as set forth in applicant's own specification. In light of the combination of Lazarus in view of the secondary teachings, the modified vessel would have rigidity beyond that of a corrugated fabric tube.

Claim Rejections - 35 USC § 102

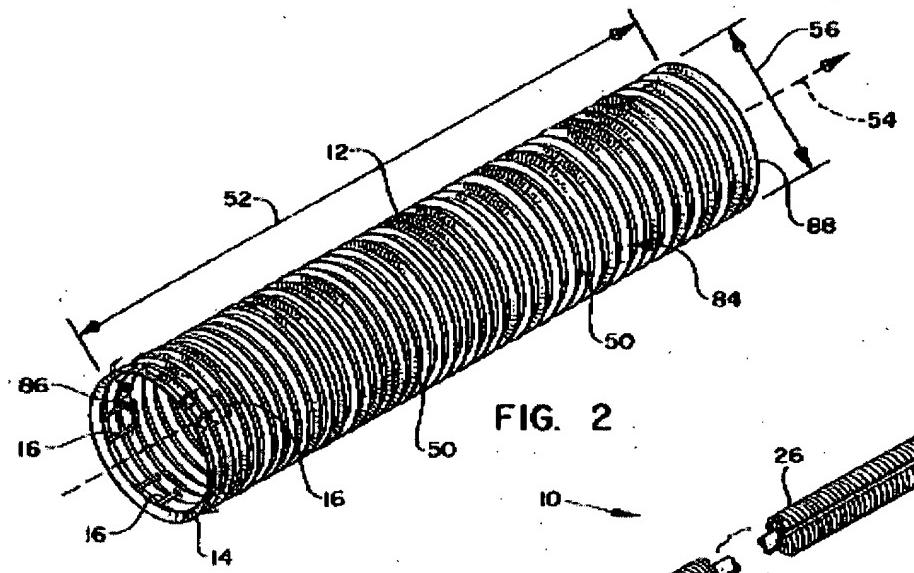
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16,18-21,22,24,31,33 -36,38-41,43-45,47-51,53-62 and 64are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lazarus [4787899].

Lazarus discloses a conduit comprising a hollow conduit having an interior and an exterior wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place.



The language "for use in a wall of a heart" and "adapted to positioned in the heart wall between a coronary vessel and a chamber in the heart" is directed to a method for using the "bypass conduit" and does not, in itself serve to further limit the structure of the conduit. Lazarus discloses a conduit that is for use in a lumen (eg. blood vessel or artery). The properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart. Applicant argues that Lazarus is silent as to the sufficiently rigid to remain open during both systole and diastole. If the vessel of Lazarus did not possess sufficient

rigidity, the vessel would collapse and not perform the function of a conduit for blood flow. Though Lazarus is silent as to the rigidity, it appears that when used in the vascular system the vessel remains open during both cycles of the heart. There is no disclosure in Lazarus which would preclude the use of the vessel in the wall of the heart, and therefor, the vessel of Lazarus is capable of performing the recited function. Applicant argues that the material of Lazarus is not necessarily material that could remain open in a heart wall during both systole and diastole, however applicant's device utilizes the same materials for the claimed conduit.

Claim 18 is directed to a method step of locating the left ventricle as the chamber. The claim does not further limit the structure or function of the device.

Claim 19, see barbs as illustrated in figures 3 and 4 of Lazarus.

Claims 20 and 21, the function of the barbs, as disclosed by Lazarus, perform the function of anchoring the conduit to a soft tissue. The claims are directed to a method step for locating the anchor to a particular tissue and does not serve as further limiting the structure of the device as claimed.

Claim 24, the claim is similar to claim 16 and is broadly readable on Lazarus. The recitation of "a vessel supporting mechanism does not distinguish over the barbs of Lazarus.

Claim 31, see rejection to claim 21 supra.

Claim 34, see lumen 12.

Claim 36, the conduit of Lazarus is designed to remain open during both systole and diastole and therefor meets the functional limitation of the claim.

Claim 38, the conduit of Lazarus is deformable so as to conform to the interior surface of the tissue in which it is placed.

Claim 39, the barbs are configured for attaching to the inner surface of the tissue.

Claims 51,54,56,57,58,59,60,61,62 and 64, see rejections supra corresponding to the particular claimed subject matter in each claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16,18-21,22,24,31,33-36,38-41,43-45,47-51,53-62 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus [4787899] in view of either of Robinson [4604762] or Lee [5123917].

While the device of Lazarus does not have additional supporting structures to aid in biasing the conduit to a non-collapsed position, each of Robinson and Lee teach the addition of flexible rings along the length of the conduit to provide strength to the conduit to resist collapsing of the lumen. To add supporting rings along the conduit of Lazarus to provide additional strength for biasing the lumen into an open position would have been obvious to one with ordinary skill in the art from the teachings of either of Lee or Robinson.

Claims 18-21,31,33-36,38-41,43-45,47-51,53-62 and 64, see rejections supra (see 102 rejections under Lazarus) corresponding to the particular claimed subject matter in each claim.

Claims 37,46 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus [4787899] as modified and as applied to the claims above, and further in view of Bowen [2127903].

Bowens shows various known configuration of conduits used for augmentation and/or reconstruction of various in vivo tissues, organs and vessels. To form the conduit of Lazarus in a non-linear conduit as illustrated in figures 6,7 and 7a to better meet the in vivo applications and tissue requirements would have been obvious to one with ordinary skill in the art based upon routine surgical considerations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

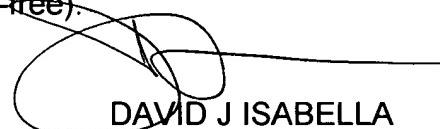
Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
12/13/2006